

Drug Enforcement Administration

[Docket No. DEA-1088]

Bulk Manufacturer of Controlled Substances Application: Eli-ElSohly Laboratories

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Eli-ElSohly Laboratories, has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to https://www.regulations.gov and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on https://www.regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on August 19, 2022, Eli-ElSohly Laboratories, 5 Industrial Park Drive, Oxford,

Mississippi 38655-5343, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled Substance	Drug Code	Schedule
Marihuana Extract	7350	I
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Tetrahydrocannabinols	7370	I
Dihydromorphine	9145	I
Amphetamine	1100	II
Methamphetamine	1105	II
Cocaine	9041	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Ecgonine	9180	II
Thebaine	9333	II

The company plans to manufacture the listed controlled substances for product development and reference standards. In reference to drug codes 7360 (Marihuana) and 7370 (Tetrahydrocannabinols), the company plans to isolate these controlled substances from procured 7350 (Marihuana Extract). In reference to drug code 7360, no cultivation activities are authorized for this registration. In reference to drug code 9333 (Thebaine), the company plans to manufacture a Thebaine derivative. No other activities for these drug codes are authorized for this registration.

Kristi O'Malley,

Assistant Administrator.

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